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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/298,523	04/23/1999	DAVID E. BRILES	454312-3140	2114

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/298,523

Applicant(s)

BRILES ET AL.

Examiner

Nita M. Minnifield

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 4-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed August 13, 2001 is acknowledged and has been entered. Claims 1 and 3 have been amended. Claims 1-3 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and comments with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. This application contains claims 4-27 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. The preliminary amendment filed October 25, 2000, requesting amendment to the specification (see pages 2-8 of the amendment) was not entered. A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the number and nature of the amendments render it difficult to consider the application or arrange the papers for printing or copying.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

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5. The Office acknowledges Applicants' Deposit information, however the address for the ATCC is not correct. Correction is required. The current address is set forth below:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

6. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of epitope or epitopic region of PspC; where are these regions within the PspC? Have they been defined by specific amino acid sequences? What specific portion of the proline-rich region is considered the epitope of epitopic region of PspC?

7. Claims 1-3 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Brooks-Walter (ASM 1997 abstract), Briles et al (1997 Microbial Drug Resistance; review presented in 1996) or Swiatlo et al (1997).

The claims are directed to an isolated polypeptide comprising at least on epitope or epitopic region of PspC. It is noted that specification defines the epitope or epitopic region of PspC to be the proline rich region (see p. 35; p. 7) or the alpha helical region (see p. 7).

Brooks-Walter discloses a PspC protein that is highly antigenic, and that has a proline rich region and alpha helical region.

Briles et al disclose a PspC protein that has an N-terminal alpha helical domain, a proline-rich domain (p. 406, cols. 1 and 2).

Swiatlo et al discloses an isolated protein having a proline-rich region and alpha-helical coding domain (abstract). It is noted that the "pspA-like" protein is now called PspC.

The prior art discloses the claimed isolated polypeptide. Since the Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the polypeptide of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptide). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's arguments filed August 13, 2001 have been fully considered but they are not persuasive. Applicants have asserted that the art is not proper prior art. Applicants have asserted claim of priority back to 1995 via 08/529055. However, Applicants have not provided evidence of enablement or proper description that the claimed invention was set forth in the specification of application 08/529055. It is noted that the specification now states that this application is a CIP of 08/714741, filed 1996; which is a CIP of 08/529055, filed 1995. Applicants' are requested to provide copies of these specifications so that priority can be determined.

It is noted that the prior art discloses a PspC with alpha helical domains and a proline-rich domain, which is the same as set forth by Applicants in the specification as the epitope or epitopic region of the PspC (specification, pp. 7-8). The claimed invention is set forth in the prior art.

Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sequence of pspC gene, sequence of Pspc protein) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

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limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. No claims are allowed.
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

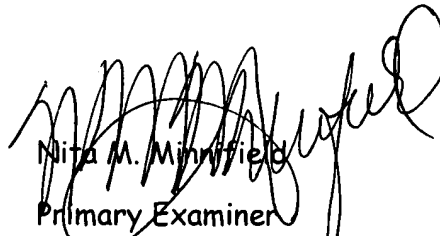
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nita M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Nita M. Minnifield
Primary Examiner
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November 19, 2001